

conspicuous warning statement in heavy block type on clearly contrasting background, such as: "Warning—Keep this and all medicines out of children's reach. In case of accidental overdose, contact a physician immediately," or "Warning—Keep out of the reach of children," except that if the article is an aspirin preparation, it shall bear the first of these warning statements.\* \* \*

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(g)(1) The label of any drug containing more than 5 percent methyl salicylate (wintergreen oil) should bear a conspicuous warning such as: "Warning: Do not use otherwise than as directed. Keep out of the reach of children to avoid accidental poisoning."

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(h)(1) The labeling of orally or rectally administered over-the-counter aspirin and aspirin-containing drug products subject to this paragraph is required to prominently bear a warning. The warning shall be as follows: "WARNING: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome, a rare but serious illness reported to be associated with aspirin."

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**§ 201.315 Over-the-counter drugs for minor sore throats; suggested warning.**

The Food and Drug Administration has studied the problem of the labeling of lozenges or troches containing a local anesthetic, chewing gum containing aspirin, various mouth washes and gargles and other articles sold over the counter for the relief of minor irritations of the mouth or throat. It will not object to the labeling of suitable articles of this type "For the temporary relief of minor sore throats", provided this is immediately followed in the labeling with a warning statement in prominent type essentially as follows: "Warning—Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by physician."

**§ 201.316 Drugs with thyroid hormone activity for human use; required warning.**

(a) Drugs with thyroid hormone activity have been promoted for, and continue to be dispensed and prescribed for, use in the treatment of obesity, although their safety and effectiveness for that use have never been established.

(b) Drugs for human use with thyroid hormone activity are misbranded within the meaning of section 502 of the Federal Food, Drug, and Cosmetic Act unless their labeling bears the following boxed warning at the beginning of the "Warnings" section:

Drugs with thyroid hormone activity, alone or together with other therapeutic agents, have been used for the treatment of obesity. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

[43 FR 22009, May 23, 1978]

**§ 201.317 Digitalis and related cardiotonic drugs for human use in oral dosage forms; required warning.**

(a) Digitalis and related cardiotonic drugs for human use in oral dosage forms have been promoted for, and continue to be dispensed and prescribed for, use in the treatment of obesity, although their safety and effectiveness for that use have never been established.

(b) Digitalis and related cardiotonic drugs for human use in oral dosage forms are misbranded within the meaning of section 502 of the Federal Food, Drug, and Cosmetic Act unless their labeling bears the following boxed warning at the beginning of the "Warnings" section:

Digitalis alone or with other drugs has been used in the treatment of obesity. This use of digoxin or other digitalis glycosides is unwarranted. Moreover, since they may cause potentially fatal arrhythmias or other adverse effects, the use of these drugs in the treatment of obesity is dangerous.

(c) This section does not apply to digoxin products for oral use, which shall be labeled according to the requirements of § 310.500 of this chapter.

[43 FR 22009, May 23, 1978]

**§ 201.319 Water-soluble gums, hydrophilic gums, and hydrophilic mucilloids (including, but not limited to agar, alginic acid, calcium polycarbophil, carboxymethylcellulose sodium, carrageenan, chondrus, glucomannan ((B-1,4 linked) polymannose acetate), guar gum, karaya gum, kelp, methylcellulose, plantago seed (psyllium), polycarbophil, tragacanth, and xanthan gum) as active ingredients; required warnings and directions.**

(a) Reports in the medical literature and data accumulated by the Food and Drug Administration indicate that esophageal obstruction and asphyxiation have been associated with the ingestion of water-soluble gums, hydrophilic gums, and hydrophilic mucilloids including, but not limited to, agar, alginic acid, calcium polycarbophil, carboxymethylcellulose sodium, carrageenan, chondrus, glucomannan ((B-1,4 linked) polymannose acetate), guar gum, karaya gum, kelp, methylcellulose, plantago seed (psyllium), polycarbophil, tragacanth, and xanthan gum. Esophageal obstruction and asphyxiation due to orally-administered drug products containing water-soluble gums, hydrophilic gums, and hydrophilic mucilloids as active ingredients are significant health risks when these products are taken without adequate fluid or when they are used by individuals with esophageal narrowing or dysfunction, or with difficulty in swallowing. Additional labeling is needed for the safe and effective use of any OTC drug product for human use containing a water-soluble gum, hydrophilic gum, or hydrophilic mucilloid as an active ingredient when

marketed in a dry or incompletely hydrated form to include, but not limited to, the following dosage forms: capsules, granules, powders, tablets, and wafers.

(b) Any drug products for human use containing a water-soluble gum, hydrophilic gum, or hydrophilic mucilloid as an active ingredient in an oral dosage form when marketed in a dry or incompletely hydrated form as described in paragraph (a) of this section are misbranded within the meaning of section 502 of the Federal Food, Drug, and Cosmetic Act unless their labeling bears the following warnings (under the subheading "Choking") and directions:

"Choking" [highlighted in bold type]: Taking this product without adequate fluid may cause it to swell and block your throat or esophagus and may cause choking. Do not take this product if you have difficulty in swallowing. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention;" and

"Directions" [highlighted in bold type]: (Select one of the following, as appropriate: "Take" or "Mix") "this product (child or adult dose) with at least 8 ounces (a full glass) of water or other fluid. Taking this product without enough liquid may cause choking. See choking warning."

(c) After February 28, 1994, any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce, or any such drug product that is repackaged or relabeled after this date regardless of the date the product was manufactured, initially introduced, or initially delivered for introduction into interstate commerce, that is not in compliance with this section is subject to regulatory action.

[58 FR 45201, Aug. 26, 1993, as amended at 64 FR 13292, Mar. 17, 1999]

EFFECTIVE DATE NOTE: At 64 FR 13292, Mar. 17, 1999, § 201.319 was amended by revising paragraph (b), effective Apr. 16, 1999. For the convenience of the user the superseded text is set forth as follows: